Summer 2014

Tempus fugit, the new academic year is fast approaching; whatever happened to the lazy days of summer? Take a look for specific changes and suggestions, below, and please check our ongoing improvements to the website.

Look for details about this year’s Human Subjects’ Protection conference at the bottom of this message.

If you have a suggestion that will help us to help you, please contact us at research.compliance@uc.edu.

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BIOSAFETY NEWS

Training Requirements
Viral Vector Online Training—Personnel listed on Institutional Biosafety Committee (IBC) protocols involving viral vectors need to complete the newly available online training prior to the approval of protocols. This training consists of five interactive modules which can be found at http://researchcompliance.uc.edu/Biosafety/Training/ViralVectorWebtraining.aspx. Once the applicable training modules are reviewed (Module 1 plus any combination of Modules 2-5, depending on which agents are listed on the protocol), an assurance form (available link at our website) should be completed and forwarded to the Biosafety Office at inbiocom@ucmail.uc.edu.

OSHA Blood Borne Pathogens Training—PIs and authorized personnel listed on protocols that include experiments with human-derived materials must have updated OSHA Blood Borne Pathogens training (BBP). This training is required both at the time of initial work assignment and at least every 12 months thereafter. BBP training is available at http://www.ehs.uc.edu/itc/courses.asp#.

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EXPORT CONTROLS

Questions to Consider
Are you working on a collaboration effort with a foreign institution, person, government or company? Do you REALLY know the institution you are visiting? Do you REALLY know the person on the other end of your phone call or e-mail? There are U.S. and foreign lists of entities (‘restricted party’ lists), which include institutions and individuals that are prohibited or restricted from certain activities. A restricted party screening must take place to ensure that no one is doing business (consulting/presenting/teaching, etc.) with entities on one of these lists. Depending on the transaction, it may be illegal to engage in certain activities with entities on any of the lists.

UC utilizes an online tool, Visual Compliance, to conduct Restricted Party Screenings. If you are collaborating with a foreign person, institution or other entity, and have not pursued an official agreement, contract or other document that is reviewed by the Office of General Counsel or Sponsored Research Services, please contact the Export Control Office (exportco@uc.edu).

Also, if you are travelling to a foreign institution for a presentation or activity, please make sure they are screened in Visual Compliance before proceeding. Some departments or colleges might want to designate one or two people to screen for their faculty and staff. If you do not have access to the software tool, please contact exportco@uc.edu to have your account set up and training provided.

IACUC UPDATE

CO2 Euthanasia Systems
During the fall semi-annual inspections, the Institutional Animal Care and Use Committee (IACUC) will be evaluating all CO2 euthanasia systems to ensure compliance with the AVMA Guidelines on Euthanasia of Animals: 2013 Edition. This requires the use of a euthanasia system which provides a 20 to 30 percent displacement rate. If you have not already brought your system into compliance, we encourage you to contact LAMS for assistance.

HUMAN RESEARCH PROTECTION PROGRAM NEWS

HIPAA and Informed Consent
The UC Institutional Review Board (IRB) will release a revised Medical Informed Consent Document (ICD) template in August, which includes language that satisfies the standards of the HIPAA Privacy Rule for individual authorization to use and disclose protected health information (PHI) for research purposes. Investigators will use the combined ICD to obtain informed consent and individual authorization from participants in studies conducted through UC Health that may obtain, create, use, and/or disclose PHI. This combined ICD will eliminate the need for a stand-alone HIPAA authorization form, reducing the administrative burden for participants and research staff. The combined ICD may not be used for studies conducted at the Cincinnati Department of Veterans Affairs Medical Center.

Reliance on Central IRBs
Form I is required for ePAS submission requesting reliance on a commercial IRB. The types of research that will not be approved for reliance includes Phase I and Phase Ib, unless the central IRB is the National Cancer Institute cIRB. Also, UC is pleased to announce the addition of Western IRB for submission of funded pharmaceutical protocols. For more information, e-mail IRB@ucmail.edu.

CITI Training Refresher Courses
If you have not already, you may soon begin receiving e-mail notices directly from the CITI system when the three-year expiration date of your CITI training is getting close. The notices are triggered by the completion dates of the original courses so separate notices will be sent for each course. Training expires with the calendar year; please follow the retraining options once you have logged on to CITI.
HRPP Policy and Procedure Updates
We try to minimize the number of emails that we send, while also working to keep you informed. Please always verify that you are relying on current forms, policies and procedures; rely on the website which lists the version date. Updates to the HRPP policies and procedures are now available at [http://ahc-sharepoint.uc.edu/hrp_policies/HRP%20Policies/Forms/Public.aspx](http://ahc-sharepoint.uc.edu/hrp_policies/HRP%20Policies/Forms/Public.aspx).

Emergency Use of a Drug or Device
All reporting activities must be done in ePAS, because this system is now serving as the primary source documentation for IRB and HRPP activities. If IRB approval cannot be obtained in time to prevent serious harm to a patient and the drug or device is administered without prior IRB approval, then it must be reported to the IRB with a separate emergency use submission and a reportable event in ePAS. Following submission, send an e-mail in Outlook to notify your HPA of the submission.

REMINDER: Exempt Studies in Researcher’s Gateway Are Expiring
Whether a human subjects research study is exempt or not, all UC IRB policies and procedures must be followed, including the submission of study amendments. Certain modifications may result in the reclassification of the research to nonexempt status. For those researchers who have active exempt protocols, you will have until Sept. 1, 2014, to close those studies or move them into the ePAS system. If the applicable study has not been moved into the ePAS system by that time, then subsequent amendments must be preceded by a new study submission in the ePAS system.

Closing Conversion Window in ePAS
As we approach two years in ePAS, the status of those studies that had not been converted into ePAS have been changed to withdrawn. A new ePAS submission will be required to proceed with study activities.

Tips
Tip #1
Reporting requirements for each research site may include some variation depending on the IRB, sponsor, department SOPs and requirements of individual medical facilities. Include documentation in the study file justifying determinations for events, such as unanticipated problems, in order to prevent misunderstandings during quality assurance reviews. Discuss potential contradictions or conflicts during research staff meetings.

Tip #2
When conducting an inpatient research study, consider performing a practice or “dry run” before starting recruitment efforts in order to ensure that the details of study procedures are complete and accurate.

Tip #3
The principal investigator is responsible for the conduct of the clinical trial at the research site including the selection and training of qualified staff to perform trial related duties. To facilitate the process of selection and training study personnel, principal investigators should be knowledgeable and/or obtain training in how to prepare and maintain accurate records, assess and report adverse events, and maintain regulatory compliance overall.

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Please join us Friday, September 12, for our 16th annual human subjects’ protection conference.

This year’s conference, entitled Human Subjects’ Protection: Don’t Stop Believin’, will once again take place at the Northern Kentucky Convention Center and will feature a diverse group of speakers discussing cutting edge topics such as:

- Ethical issues in the clinical translation of stem cell research
- IRB review of international research
- History of the research ethics and regulation field
- Consent privacy and data sharing in the age of the genome
- What online studies tell us about the future of consent procedures and participant identify verification
- Valid informed consent and using “teach back” in the research setting

Co-sponsored by the University of Cincinnati, Schulman Associates IRB, Cincinnati Children’s Hospital Medical Center, and the University of Kentucky, our 2014 conference promises to be another engaging and informative event for members of the research community.

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education.

Physician: Cincinnati Children’s Hospital Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. This activity has been approved for AMA PRA Category 1 Credit™.

Nursing: Contact hours will be awarded to nurses who attend the entire program and complete an evaluation tool.